REMARKS

The Office Action of August 27, 2003, has been received and reviewed. Claims 5-7, 10-22, and 25-33 are pending in the application. Claims 6, 11-13, 23, 24 and 26 have been canceled without prejudice or disclaimer.

Claims 5-7 and 10-22 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Wensvoort *et al.* in view of Moormann *et al.* Claims 25 and 29-31 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Wensvoort *et al.* Claims 29-31 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Moormann *et al.* Claims 5-7, 10-12, 14-22, 25 and 27-31 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly having insufficient written description relative to the breadth of the claims. Claim 26 stands objected to. Claims 5-7, 10-22 and 25-31 stand provisionally rejected under the judicially created doctrine of obviousness type double patenting. All amendments are made without prejudice or disclaimer. Reconsideration is respectfully requested.

Interview:

Applicants thank the Examiner for the courtesy extended at the personal interview conducted November 20, 2003. Applicants found the interview helpful in more fully understanding the rejections. The applicants have amended the claims, which as discussed at the interview should overcome the rejections of record. Thus, the applicants respectfully submit that the claims are in condition for allowance.

Support for Claim Amendment:

Support for the claim amendments can be found throughout the specification, for example, at paragraphs 16, 17, 51 and 53.

Support for claim 16 can be found throughout the specification, for example, at paragraph 53 which discloses PRRSV having the orthologous nucleocapsid protein of LDV substituted for ORF 7.

Claim Objection:

Claim 26 stands objected to for depending from a canceled claim. Claim 26 has been canceled without prejudice or disclaimer, thereby mooting the objection.

35 U.S.C. § 103(a):

Claims 5-7 and 10-22 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Wensvoort *et al.* in view of Moormann *et al.*

The Office states that Wensvoort *et al.* discloses *in vitro*-transcription, broadly defined to include transcription in cell culture, of a LV genome 14.5 to 15.5 Kb in length. The applicants note that this range is disclosed as the apparent molecular size based on a neutral agarose gel (page 7, lines 15-18), which does not provide an accurate size determination (page 27, lines 1-4; stating that "[a]lthough no accurate size determination can be performed in neutral agarose gels ...."). Thus, the actual molecular size of the genome disclosed in Wensvoort *et al.* is 15,088 basepairs (page 28, lines 18-21).

Claim 5, as amended, recites an *in vitro*-transcribed RNA of a cDNA copy of an Porcine Reproductive and Respiratory Syndrome (PRRS) virus genome lacking genetic information in any of ORFs 1a, 1b and/or 2-7. Wensvoort *et al.* does not teach or suggest an *in vitro*-transcribed RNA of a cDNA copy of a PRRS virus. Furthermore, Moormann *et al.* does not disclose an *in vitro*-transcribed RNA of a cDNA copy of a PRRS virus genome. Thus, Wensvoort *et al.* and Moormann *et al.*, individually or in combination, do not teach or suggest all of the claim elements. Thus, the applicants respectfully submit that claim 5 is not obvious over Wensvoort *et al.* in view of Moormann *et al.* Applicants respectfully request reconsideration and withdrawal of the rejection.

Claim 6 has been canceled without prejudice or disclaimer, thereby mooting the rejection.

Claim 7 recites a cell culture with or transfected with an isolated recombinant nucleic acid comprising at least one full-length DNA copy or in vitro-transcribed RNA copy of an RNA virus's genome, wherein the RNA virus's genome is PRRS virus. As discussed herein, neither Wensvoort *et al.* nor Moormann *et al.* teach or suggest a cell culture with or transfected with an

isolated recombinant nucleic acid comprising at least one full-length DNA copy or *in vitro*-transcribed RNA copy of an PRRS virus's genome. Thus, Wensvoort *et al.* and Moormann *et al.*, individually or in combination, do not teach or suggest all of the claim elements. Therefore, the applicants respectfully submit that claim 7 is not obvious over Wensvoort *et al.* in light of Moormann *et al.* Reconsideration and withdrawal of the rejection is respectfully requested.

Claim 10, as amended, recites in part "A recombinant DNA molecule comprising an infectious clone based upon Porcine Reproductive and Respiratory Syndrome virus's genome, said infectious clone produced by a process comprising: producing a recombinant nucleic acid comprising a nucleic acid sequence selected from the group consisting of an *in vitro*-transcribed RNA copy of the RNA virus's full length genome and DNA complementary to the RNA virus's full length genome." Neither Wensvoort *et al.* or Moormann *et al.* teach or suggest a recombinant DNA molecule comprising an infectious clone based upon PRRS virus's genome. Therefore, the applicants respectfully submit that claim 10 is not obvious over Wensvoort *et al.* in light of Moormann *et al.* Reconsideration and withdrawal of the rejection is respectfully requested.

Claims 11-13 have been canceled without prejudice or disclaimer, thereby mooting the rejection.

Claims 14-22 and 27 recite a genetically modified RNA virus based upon a PRRS virus's genome, said genetically modified RNA virus produced by a process comprising: transfecting a host cell with a recombinant nucleic acid comprising a nucleic acid sequence selected from the group consisting of an *in vitro*-transcribed RNA copy of the PRRS virus's full length genome, an *in vitro*-transcribed RNA copy of the PRRS virus genome but lacking the genetic information needed to produce enveloped, infectious RNA virus, DNA complementary to the PRRS virus's full length genome, and DNA complementary to the PRRS virus genome, but lacking genetic information needed to produce enveloped, infectious PRRS virus; wherein the host cell is not susceptible to infection with said PRRS virus, to produce said genetically modified RNA virus.. Neither Wensvoort *et al.* nor Moormann *et al.* teach or suggest transfecting a nucleic acid derived from a PRRS virus into a host cell not susceptible to infection with the RNA virus. Neither

Wensvoort *et al.* nor Moormann *et al.*, individually or in combination, teach or suggest all of the claim elements. Therefore, the applicants respectfully submit that the claims are not obvious over Wensvoort *et al.* in light of Moormann *et al.* Reconsideration and withdrawal of the rejection is respectfully requested.

35 U.S.C. § 102(b):

Claims 25 and 29-31 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Wensvoort *et al.* Amended claim 25 is directed to a DNA molecule complementary to an PRRS genome, but lacking genetic information encoding an envelope protein of said PRRS virus. Wensvoort *et al.* does not disclose a DNA molecule complementary to a PRRS genome, but lacking genetic information encoding an envelope protein of the PRRS virus. Thus, the applicants respectfully submit that Wensvoort *et al.* does not anticipate claim 25.

Claims 29-31 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Wensvoort *et al.* Amended claim 29 recites an infectious clone based upon a positive strand RNA virus's genome, wherein said RNA virus is ... PRRS virus, said infectious clone produced by a process comprising: producing a recombinant nucleic acid comprising ... an extracellularly in vitro-transcribed RNA copy of the RNA virus's full length genome, an in vitro-transcribed RNA copy of the RNA virus genome but lacking genetic information encoding the at least one envelope protein, DNA complementary to the RNA virus's full length genome, and DNA complementary to the RNA virus genome, but lacking genetic information encoding the at least one envelope protein, wherein the RNA virus's genome is greater than about 15 kb. Wensvoort *et al.* does not disclose an infectious clone based upon a PRRS virus. Thus, the applicants respectfully submit that Wensvoort *et al.* does not anticipate the claim.

Likewise, amended claims 30 and 31 recite a composition for raising an immune response against a ... [PRRS] virus, ... comprising: recombinant nucleic acid selected from the group consisting of" and "a cell culture containing a [PRRS] positive strand RNA virus's genome ... , said cell culture infected with or transfected with recombinant nucleic acid selected from the

group consisting of," respectively. Claims 30 and 31 go on to recite that the recombinant nucleic acid is selected from the group consisting of: an *in vitro*-transcribed RNA copy of the positive strand RNA virus genome, but lacking the genetic information encoding the at least one envelope protein; DNA complementary to the positive strand RNA virus's full length genome; and DNA complementary to the positive strand RNA virus genome, but lacking genetic information encoding the at least one envelope protein, which are not disclosed or suggested by Wensvoort *et al.* Therefore, the applicants respectfully submit that Wensvoort *et al.* does not disclose all of the claim elements and does not anticipate the claim.

Because Wensvoort *et al.* does not disclose all of the elements present in claims 25 and 29-31, the applicants respectfully submit that the reference does not anticipate the claims. Reconsideration and withdrawal of the rejection is respectfully requested.

Claims 29-31 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Moormann *et al.* Moormann *et al.* does not disclose a PRRS virus as recited by these claims. Because Moormann *et al.* does not disclose all of the elements present in claims 29-31, the applicants respectfully submit that the reference does not anticipate the claims. Reconsideration and withdrawal of the rejection is respectfully requested.

35 U.S.C. § 112, first paragraph:

Claims 5-7, 10-12, 14-22, 25 and 27-31 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly having insufficient written description relative to the breadth of the claims. To comply with the written description requirement of 35 U.S.C. § 112, first paragraph, the specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonable conclude that the inventor had possession of the claimed invention.

While the applicants respectfully disagree that the specification lacks sufficient written description, the Applicants have amended the claims to recite PRRS virus. The Office has acknowledged that the specification provides sufficient written description relating to the production of a recombinant PRRS virus (page 6 of Paper 10, stating that the "specification shows the production of a recombinant ... [PRRS] virus ...."). Thus, the applicants submit that

the claims, as amended, are supported by a written description satisfying the requirements of *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997).

Double Patenting:

Claims 5-7, 10-22 and 25-31 stand provisionally rejected under the judicially created doctrine of obviousness type double patenting. Applicants herewith submit a terminal disclaimer.

CONCLUSION

Applicants have amended the claims as discussed at the interview conducted November 20, 2003, which amendments were acknowledged to overcome the rejections of record. Thus, the applicants respectfully submit that the claims are in condition for allowance. Should questions remain after entry of the amendments and consideration of the remarks, the Office is kindly invited to contact the applicant's representative at the number provided herein.

Respectfully submitted,

G. Scott Dorland, Ph.D.
Registration No. 51,622
Attorney for Applicants
TRASKBRITT, P.C.
P.O. Box 2550
Salt Lake City, Utah 84110-2550
Telephone: 801-532-1922

Date: February 4, 2004
GSD/gsd